



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

JAN 13 2003

Indian Health Service
Rockville MD 20852

TO: Executive Director
National Acquisitions Center
Department of Veterans Affairs

FROM: Interim Director

SUBJECT: Comments on the Proposed Modification of the Department of Veterans Affairs'
Pharmaceutical Prime Vendor Contract

Thank you for the opportunity to provide comments on the proposed modification to the Department of Veterans Affairs' (VA) Pharmaceutical Prime Vendor (PPV) contract between the VA and AmerisourceBergen. The proposed contract modification, when signed by the VA and AmerisourceBergen, changes the current VA'S PPV contract-setting terms and conditions under which Tribes can directly access services of the VA's PPV contract as they are now allowed to do under Section 450j(k) of the Indian Self-Determination and Education Assistance Act (ISDA), Public Law 93-638. Once the modification is approved and the Interagency Agreement between the VA and the Indian Health Service (IHS) is changed, each Tribe or Tribal organization opting to exercise the modification would sign a separate agreement with AmerisourceBergen.

The IHS has consulted with Tribes and Tribal organizations regarding the proposed contract modification, and I have attached the resulting comments. Please contact CAPT Robert E. Pittman, Principal Pharmacy Consultant, IHS, if you have questions or concerns regarding any of these comments. He can be reached on (301) 443-1190.

Charles W. Grim, DDS
Charles W. Grim, D.D.S., M.H.S.A
Assistant Surgeon General

Attachment

GENERAL COMMENTS

The Pharmaceutical Prime Vendor (PPV) contract modification should state that each Tribe or Tribal organization choosing to exercise this option must sign a separate contract with AmerisourceBergen. The contract would reference the terms and conditions set out in the contract modification as the basis for Tribal direct-access to the VA's PPV services. It should also clarify that (1) in carrying out an Indian Self-Determination and Education Assistance Act (ISDA), Public Law 93-638, agreement, a Tribe is deemed an executive agency and part of the IHS for purposes of eligibility for the VA discount program under section 603 of the Veterans Health Care Improvement Act; and (2) the Tribe does **not** enter into a direct relationship with AmerisourceBergen **as part of the Indian Health Service (IHS)**, thereby making the IHS liable for contract claims. The contract modification should clarify that it creates no contractual or other liability on the part of the IHS to AmerisourceBergen or the customer Tribe.

The contract modification should contain a termination provision allowing a Tribe to terminate the direct-access relationship with AmerisourceBergen. The option to access the VA's PPV through the IHS remains available to the Tribe if the Tribe decides to terminate its direct-access relationship.

SECTION 1 – PRICE OF GOODS

The contract should specifically state that the "Average Monthly Volumes" apply to each delivery location rather than to each entity, since a Tribe may have more than one facility site and may expect to be able to pool the purchase dollars from these sites to reduce the distribution fee (even though medications are being sent directly to several different locations).

The clause grandfathering in Tribes at a more favorable price should explicitly state that the Tribes that have been using an IHS intermediary will have the benefit of the IHS pricing and distribution fees. The clause should also detail the current IHS pricing, delivery-fees payment schedule, etc., into which these Tribes will be grandfathered.

The modification should reference the VA's PPV contract sections that pertain to credit for medications not shipped (shortages) or damaged goods, and to prepayment terms.

SECTION 2 – MINIMUM PURCHASES

The IHS requests the VA and AmerisourceBergen to review the \$5,000 per month minimum order for possible ways to reduce this amount so that smaller facilities can participate in the VA's PPV contract.

There are concerns about the "refuse to ship" part in this section. As part of the 30-day written notification process informing a Tribe that the Agreement is being terminated, a statement should be added referring the Tribe to an intermediary that can place orders with the VA's PPV for the Tribe.

SECTION 3 – DELIVERIES

The modification needs to reference the VA's PPV contract or provide additional clarification about the delivery process for sites ordering less than \$50,000 worth of medication per month. For example, if a site only has one delivery per week (orders between \$5,000 and \$15,000), will these orders be held until a certain day of the week, or can they be shipped immediately with future orders held for the following week?

The clause grandfathering in Tribes at a more favorable delivery schedule should explicitly state that the Tribes that have been using an IHS intermediary will have the benefit of the IHS delivery schedule. The clause should also detail the current IHS delivery schedule.

SECTION 4 – COST REPORTING

No changes requested.

SECTION 5 – PROPRIETARY SOFTWARE

No changes requested.

SECTION 6 – HARDWARE

Reference the section of the VA'S PPV contract that states the conditions under which the hardware is originally received.

SECTION 7 – PROPRIETARY SOFTWARE/HARDWARE LIMITED WARRANTY

Reference the VA's PPV contract sections that provide for fixing or replacing defective software or hardware beyond the warranty period. If there is a cost for replacement or for extending the warranty, it should be specified.

SECTION 8 – ACCESS TO ORDERING MECHANISMS

No changes requested.

SECTION 9 – COMPLIANCE WITH LAW

Add a reference to Section 105(k) of the Indian Self-Determination and Education Assistance Act, 25 United States Code (U.S.C.) 450j(k), in the first sentence.

If there are additional reasons for terminating a contract or situations under which the VA's PPV would refuse to ship medication orders, they should be detailed or referenced in the contract. Appropriate sections in the VA's PPV contract need to be referenced identifying the process to appeal contract termination or the removal of any contract pricing.

SECTION 10 – INDEMNIFICATION

Tribes and Tribal organizations are concerned about the indemnification clause in the proposed modification. Some Tribes believe this clause exposes them to potentially high costs without defining what these costs are or limiting a Tribe's potential liability. Several Tribes believe this issue is covered by the Federal Tort Claims Act (FTCA) when a Tribe is carrying out its ISDA Agreement. The IHS believes the FTCA would not cover these issues. This section needs additional discussion.

SECTION 11- LIMITATION OF LIABILITY

No changes requested.

SECTION 12 – INSOLVENCY

The Tribes need to be notified when the VA's PPV contractor is terminating the contract and withholding shipment of medications. Additionally, the Tribe needs to be referred to an IHS intermediary to ensure there is some means of acquiring the medication.

SECTION 13 – INSURANCE

By statute, Tribes and their employees carrying out contracts and compacts under the ISDA are deemed part of the Public Health Service for purposes of the FTCA, and the Federal Government would be substituted as the defendant with respect to claims cognizable under the FTCA. See implementing regulations at 25 C.F.R. Part 900, Subpart M. Section 13 requires professional liability insurance to protect AmerisourceBergen. While many Tribes contracting and compacting under the ISDA carry wraparound liability insurance that is supplemental to the FTCA coverage, we would like to discuss further whether Section 13 is necessary given the FTCA coverage.

SECTION 14 – CUSTOMER QUALIFICATIONS

No changes requested.

SECTION 15 – ENTIRE AGREEMENT

The only change requested is that "explanations" referenced in the original VA's PPV contract apply to this contract (e.g., if a definition of "Diversion" is referenced, it also applies to the modification).

SECTION 16 – SEVERABILITY

No changes requested.

SECTION 17 – WAIVERS

No changes requested.

SECTION 18 – NOTICES

No changes requested.

SECTION 19 – GOVERNING LAW

While many Tribes expressed willingness to have disputes heard in Federal or Tribal courts, none want disputes resolved under State law in State courts. On the other hand, Section 19 would preclude Tribal jurisdiction and provide that disputes between the parties be governed by the laws of the United States and the State surrounding the applicable customer's Tribal lands. While Federal jurisdiction may be a compromise, the contract modification would authorize a Tribal customer and AmerisourceBergen to enter into a private commercial contract for Tribal direct-access to prime vendor services. Federal jurisdiction and the application of Federal law to disputes under such a contract is questionable; nor may the parties provide by contract for Federal jurisdiction if it does not otherwise exist. Rather than have this section prove a stumbling block to implementation of a direct-access relationship, we suggest that jurisdictional issues be discussed further and that binding arbitration be explored as an option.